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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

## Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Dental Products Panel of the Medical Devices Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on May 10, 1999, 10:30 a.m. to 6:30 p.m., and May 11, 1999, 8 a.m. to 3 p.m.

*Location*: Holiday Inn, Walker-Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person*: Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On May 10, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a total temporomandibular joint (TMJ) prosthesis, which consists of the glenoid fossa prosthesis and the mandibular condyle prosthesis, for reconstruction of the TMJ. On May 11, 1999, the committee will discuss, make recommendations, and vote on a PMA that includes both a total TMJ prosthesis and a glenoid fossa prosthesis that can be used alone without the mandibular condyle prosthesis to reconstruct the TMJ. These PMA's

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were received in response to the final rule issued in the **Federal Register** of December 30, 1998 (63 FR 71743), requiring the filing of a PMA or a notice of completion of a product development protocol for the total TMJ prosthesis (21 CFR 872.3940), the glenoid fossa prosthesis (21 CFR 872.3950), the mandibular condyle prosthesis (for permanent reconstruction; 21 CFR 872.3960), and the interarticular disc prosthesis (21 CFR 872.3970) under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)).

*Procedure*: On May 10, 1999, from 10:30 a.m. to 5:30 p.m., and May 11, 1999, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 5, 1999. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m. on May 10, 1999, and between approximately 8:15 a.m. and 8:45 a.m. on May 11, 1999. Near the end of the committee deliberations on each day, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 5, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations*: On May 10, 1999, from 5:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding dental device issues.

FDA regrets that it was unable to publish this notice 15 days prior to the May 10 and 11, 1999, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available

at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 20, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

M A Friedman

Michael A. Friedman
Deputy Commissioner for Operations

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